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September 13, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

VIA ELECTRONIC FILING

MAIL STOP HATCH-WAXMAN PTE
Commissioner for Patents
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Alexandria, VA 22313-1450

I hereby certify that this paper or fee is being transmitted electronically to MAIL STOP HATCH-WAXMAN PTE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, through the EFS-Web Filing System, on the date specified below.

David B. Quick
Typed or Printed Name of Person Signing this Certificate

Signature

September 13, 2010
Date of Signature

In re US Patent No. 4,919,140:	Borgens, et al.
Filed	October 14, 1988
Issue Date	April 24, 1990
Title	Method And Apparatus For Regenerating Nerves

APPLICATION FOR SUBSEQUENT INTERIM PATENT TERM EXTENSION UNDER 35 USC §156(d)(5)(C) AND 37 CFR §1.710, ET SEQ.

Please find contained herein Purdue Research Foundation's request for a subsequent interim extension of United States Patent No. 4,919,140 under 35 U.S.C. *§156(d)(5)(C)* and 37 C.F.R. *§1.790*. This is the second request for subsequent interim

patent term extension (third request for interim patent term extension) filed with regard to this United States Patent No. 4,919,140 and is being filed within the period between 60 days and 30 days prior to the expiration of the second interim patent term extension which extended the term of United States Patent No. 4,919,140 to October 14, 2010. United States Patent No. 4,919,140 is owned by Purdue Research Foundation, 3000 Kent Avenue West Lafayette, Indiana 47906. Pursuant to 37 C.F.R. §1.710, et seq., the below information is provided.

A. The regulatory review period has not been completed.

B. The following includes the materials or information required by 37 C.F.R. §*1.740 and* and 37 C.F.R. §*1.741*, which was not present in the preceding interim extension application, the Amendment and Supplement to Request for Interim Patent Term Extension, the Subsequent Request for Interim Patent Term Extension (all three of which are hereby incorporated herein with all Exhibits and attachments thereto by this reference):

(1) The medical device is still currently undergoing review.

(2) This application is being filed within the window of between sixty to thirty days prior to the expiration of the term of the patent as previously extended as prescribed in 35 U.S.C. §156(d)(5)(C). By order dated October 9, 2009, the term of the OFS Patent was extended until October 14, 2010. Thus, the patent term is to expire October 14, 2010, with the last day on which the Application for filing the subsequent interim extension request falling on September 14, 2010.

(3) A brief description of the significant activities undertaken by Purdue Research Foundation, its licensees Depuy, Andara Life Sciences, Inc., Cyberkinetics Neurological

Systems, Inc. and Neurometrix and their Sponsors of studies during the applicable regulatory period with respect to the Medical Device and the significant dates applicable to such activities is attached as **Updated Exhibit F** which is intended to supplement and replace any prior **Exhibit F**.

(4) A statement that in the opinion of the Applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined, is attached as **Updated Exhibit G** which is intended to supplement and replace any prior **Exhibit G**.

(5) Purdue Research Foundation acknowledges its duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought, and the tenets of the duty of disclosure in 37 C.F.R. §1.765 relevant to the application.

(6) The prescribed $220.00 fee pursuant to 37 C.F.R. §1.20(j)(3) is being paid electronically concurrent with the filing of this application, the Director is authorized to charge any additional fee, or credit overpayment, to Deposit Account No. 09-0007 of Ice Miller LLP.

(7) Any inquiries and correspondence relating to this application should be directed to:

David B. Quick
ICE MILLER LLP
One American Square
Suite 2900
Indianapolis, IN 46282-0200

CONCLUSION

Purdue Research Foundation is asking for an interim extension of U.S. Patent No. 4,919,140 until the earlier sixty days following Regulatory Approval of the Medical Device or October 14, 2011. If there is any questions on this application, please contact the agent for the applicant, as noted above.

Respectfully Submitted

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DBQ/sg
Encl: Updated Exhibits F and G
Declaration

A brief description of the significant activities undertaken by Purdue Research Foundation and its licensees prior to and during the applicable regulatory period with respect to the Medical Device

A) Pre-regulatory Non-human trials for proof of concept and determination of safety for documentary support for IDE request as indicated in HHS Publication FDA 96-4149.

1990	First clinical trials utilizing dogs initiated to test effectiveness of original packaging design begun with device not including all of the safety features to be present on human device to aid in establishing major health effects of the medical device.
October 19, 1992	Publication on first clinical trials utilizing dogs with device not including all of the safety features to be present on human device submitted.
January 21, 1993	Publication on first clinical trials with dogs utilizing dogs with device not including all of the safety features to be present on human device accepted for publication following requested revisions.
1994	Second clinical trials on dogs begun with device including higher electrical fields than first study and safety features to be present on human device to aid in establishing major health effects of the Medical Device. Medical Device was identical to that later implanted in humans for human trials.
1998	Completed second clinical trial on dogs using device identical to that implanted in humans during human trials.
November 7, 1999	Published results of second clinical trial on dogs using device identical to that implanted in humans during human trials.

B) **Efforts to Obtain Regulatory Approval**

June 15, 1999	Documentation of Review and Approval submitted to IUPUI and Clarian Institutional Review Boards & Subcommittee Reviews for Study Number 8808.12 ("Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator." (See Appendix A).
July 6, 1999	FDA IDE manual obtained.
July 8, 1999	Preparation of IDE request started by Borgens.
circa July 1999	FDA contacted by phone to obtain information regarding IDE process.
August 17, 1999	Documentation of Review and Approval for Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator entered in minutes of IRB.
August 30, 1999	Institutional Review Board (IRB) of Indiana University School of Medicine, Department of Surgery, Department of Neurological Surgery provisionally approved clinical human trials contingent upon receipt of IDE approval.
October 5, 1999	Certification sent to IRB that all investigators had signed a letter of agreement regarding Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator.
December 9, 1999	Final approval of IRB received for Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator.
May 2, 2000	First Patient enrolled in Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator.
August 30, 2000	An application to conduct a ten person feasibility study (IDE#G000195) at Indiana University by primary investigator ("Sponsor") Scott A. Shapiro MD was approved by the FDA. Clinical Investigation begun.

March 29, 2001	Medical device implanted in B_W01 pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164). Remainder of Patient Demographic information included in Table 5 appearing on page 18 of the HDE request (attached as Appendix D) For each patient, neurological assessments were made at four time periods, prior to implant and six weeks, six months and twelve months post implant.
July 5, 2001	Fourth patient enrolled in Pilot Study for Treating Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator.
April 10, 2001	Patient #2 tested pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
May 5, 2001	Patient #3 tested pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
June 1, 2001	Patient #4 tested pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
October 23, 2001	Patient #5 tested pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
February 5, 2002	Patient #6 tested pursuant to Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).

January 7, 2004	Completion of first ten patients' involvement in Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
August 27, 2004	Sponsor received approval from FDA to enroll an additional ten patients in the Feasibility Study for Testing the Severely Injured Spinal Cord with an Extraspinal Oscillating Field Stimulator (Ref. #00-164).
October 21, 2005	Humanitarian Use Device (HUD) designation request #05-0159 submitted for Investigation Device Exemption Number pursuant to 21 CFR section 812.20.
November 1, 2005	FDA Questions
December 9, 2005	FDA Questions
February 14, 2006	CKI acquires Andara Life Science, Inc.
February 20, 2006	Additional Data/Response to Questions Submitted
March 8, 2006	Additional Data/Response to Questions Submitted
March 22, 2006	Additional Data/Response to Questions Submitted
May 5, 2006	Additional Data/Response to Questions Submitted
June 15, 2006	E-mail message from Dr. Sarah Linde-Feucht of the FDA requesting clarification as to intended use of the Medical Device
July 26, 2006	Additional Data/Response to Questions Submitted
August 31, 2006	HUD Designation Granted by FDA as IDE G000195 pusuant to Fed. FDCA section 520(m).
December 22, 2006	Human clinical investigation of Andara OFS device under IDE G00195 completed
February 16, 2007	Humanitarian Device Exemption submittal.
February 20, 2007	HDE received by FDA Center of Device and Radiological Health, Office of Device Evaluation.
February 21, 2007	Letter from Pauline Fogarty of FDA Center of Device and Radiological Health, Office of Device Evaluation, to Tim Surgenor of Cyberkinetics, Inc. indicating Original HDE application on the

	Medical Device was received February 20, 2007 and was assigned HDE number H070002.
May 9, 2007	1st Set of Questions from FDA
July 10, 2007	Response to 1st Questions
December 7, 2007	2nd Set of Questions from FDA
February 28, 2008	Meeting with FDA to clarify appropriate manner for responding to second set of Questions generated December 7, 2007
March 14, 2008	Response to 2nd Questions
June 6, 2008	FDA Questions & determination to use Clinical Panel
August 8, 2008	Package went out to Clinician Panel.
November 5, 2008	3rd Set of Questions from FDA
January 25, 2009	Notification to FDA of transfer of Sponsorship from Cyberkinetics to Neurometrix
February 2, 2009	Neurometrix requests extension to complete answers to 3rd set of questions
March 5, 2009	FDA grants extension to July 31, 2009
July 23, 2009	Neurometrix submits letter appealing 3rd Set of Questions
July 28, 2009	FDA acknowledges receipt of appeal
August 13, 2009	Phone conversation between NeuroMetrix regulatory counsel and Dr. Tillman, Director, Office of Device Evaluation regarding appeal
September 24, 2009	FDA (Mr. Hoffman) sends email with feedback on timeline for FDA's response
September 28, 2009	Phone conference with FDA (Mr. Hoffman) regarding timeline for FDA response and discussion on whether additional data would be submitted
September 30, 2009	Email to FDA (Mr. Hoffman) stating that no additional data will be submitted with supporting rationale
October 20, 2009	Scientific question from FDA regarding content of appeal
October 22, 2009	Detailed response to FDA scientific questions provided via email

October 30, 2009	Appeal response received from FDA. Maintain claim that insufficient data exists to support HDE approval
November 2009 -April 2010	Internal review of appeal response and HDE file
May 2010 – present	Preliminary work developing study protocol to provide FDA with requested data, Efforts to obtain financing for requested study.

Statement That In The Opinion Of The Applicant The Patent Is Eligible For The Extension And A Statement As To The Length Of Extension Claimed, Including How The Length Of Extension Was Determined

1. Reasons for which an interim Extension Is Available

In the opinion of Purdue Research Foundation ("PRF"), U.S. Patent No. 4,919,140 ("the OFS Patent") is eligible for a subsequent interim patent term extension pursuant to 35 U.S.C. 156(d). While PRF is only petitioning currently for a one year subsequent interim extension until the earlier of October 14, 2011 or sixty days following regulatory approval, PRF ultimately believes that it will become entitled to petition for an extension of the OFS Patent to five years from the original expiration date of October 14, 2008, i.e. until October 14, 20013, as a result of the continuing pre-market regulatory review of the Medical Device, assuming the HDE request is treated as a Premarket Approval Request that is exempt from the effectiveness requirements of Section 515 so that the date of filing of the same can be treated as the initial submission of an application "with respect to the device under section 515." The preliminary calculation of the extension term to which the OFS Patent is entitled does not include periods in which non-human clinical studies were performed to establish the major health effects and scientific basis for the utilization of the Medical Device to treat spinal cord injuries or the period of submissions seeking IRB approvals for Human Pilot Studies or Human Pilot Studies performed prior to FDA approval of the IDE on August 30, 2000, which periods may increase the number of days that the term of the OFS Patent should be extended. The reasons the applicant believes that it is entitled to an interim extension of the OFS Patent for at least one year or until sixty days after regulatory review is completed are as follows:

(a) The term of the OFS Patent has not expired before this application is submitted.

(b) The term of the Patent has been extended only twice interimly.

(c) The application for second subsequent interim patent term extension is submitted by an authorized agent of the record owner of the OFS Patent.

(d) The Medical Device has been subject to a regulatory review period before its commercial marketing or use as evident from Exhibits E (submitted with the initial Request for Interim Extension) and updated Exhibit F, attached hereto and incorporated herein).

(e) The first commercial marketing of Andara™ OFS™ System will follow the approval of request for approval for the commercial marketing or use of the Medical Device.

(f) Applicant reasonably believes that Regulatory Approval of a Humanitarian Device Exemption will be received on the Medical Device.

2. Calculation

Applicant believes that the OFS patent is eligible for a subsequent one year interim patent term extension and will, upon approval of the HDE application be eligible for the maximum five year extension from the original expiration date once regulatory review is completed. The applicant has made a determination that the OFS patent, upon receiving regulatory approval, will be eligible for an extension until October 14, 2013. The below calculation in no way should be interpreted as relinquishing Applicant's right to seek a five year extension of the term of the patent following completion of regulatory review, should there be some subsequent determination that applicant did not act with due diligence. This determination was made by:

(a) Determining the number of days in the period beginning on the date of clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under the Federal Food Drug, and Cosmetic Act = 2362 days (between August 30, 2000 and February 16, 2007).

(b) Determining the number of days in the period beginning on the date of the application was initially submitted with respect to the medical device under the Federal Food, Drug, and Cosmetic Act, and ending on the date of the filing of this application for interim extension (in view of the fact that approval of the application has yet to be received) = 1306 days (February 16, 2007 to September 13, 2010).

(c) Adding the results of paragraphs (a) and (b) = 3668 days (2362+1306).

(d) Determining the number of days in the periods of paragraphs (a) and (b) which were on and before the date on which the patent issued = 0 days.

(e) Determining the number of days in the periods of paragraphs (a) and (b) in which applicant did not act with due diligence = 0 days.

(f) Determining one half of the number of days remaining in the period defined in paragraph (a) after that period is reduced in accordance with paragraphs (d) and (e) = 1181 days (2362days/2).

(g) Subtracting the number of days determined in paragraphs (d) (e) and (f) from the number of days determined in paragraph (c) = at least 2487 days (3668-0-0-1181).

(h) Adding the number of days determined in paragraph (g) to the original term of the patent (October 14, 2008) as shortened by any terminal disclaimer = some time following August 6, 2015.

(i) Adding fourteen years to the date of approval of the application under the Federal Food, Drug, and Cosmetic Act = No earlier than September 14, 2023.

(j) Comparing the dates obtained in paragraphs (h) and (i) and selecting the earlier date = at least some time following August 6, 2015.

(k) Adding five years to the original expiration date of the OFS Patent (October 14, 2008) or earlier date set by terminal disclaimer = October 14, 2013.

(l) Comparing the dates obtained in paragraphs (j) and (k) and selecting the earlier date = October 14, 2013.

Since regulatory approval has yet to be received for the Medical Device and because the OFS Patent would be eligible for a patent term extension until October 14, 2013, if approval had been received on the date of filing this application for interim extension, in the opinion of the Applicant, the term of the OFS Patent should be extended interimly to the earlier of October 14, 2011 or sixty days following regulatory approval of the Medical Device, subject to further interim extensions of up to one year if regulatory approval is not received sixty days prior to any interim extension granted to the OFS Patent.

ICE MILLER LLP
LEGAL COUNSEL

September 13, 2010

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In re US Patent No. 4,919,140:	Borgens, et al.
Filed	October 14, 1988
Issue Date	April 24, 1990
Title	Method And Apparatus For Regenerating Nerves

DECLARATION

I, David B. Quick, an counsel attorney at Ice Miller LLP and an authorized patent attorney for Applicant, Purdue Research Foundation, submit this declaration, along with an Application for Interim Patent Term Extension Under 35 USC § 156(d) and 37 C.F.R. § 1.710, et seq. for U.S. Patent No. 4,919,140, and hereby state that:

(1) I am a patent attorney authorized to practice before the Patent and Trademark Office and have general authority from the owner to act on behalf of the owner in patent;

(2) I have reviewed and understand the contents of the application being submitted pursuant to 37 C.F.R. § 1.790;

(3) I believe the patent is subject to extension pursuant to 37 C.F.R. § 1.790;

(4) I believe an interim extension of the length claimed is fully justified under 35 U.S.C. § 156 and the applicable regulations;

(5) I believe U.S. Patent No. 4,919,140 meets the conditions for an interim extension of the term of a patent as set forth in 37 C.F.R. § 1.790.

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any extension of patent term issuing thereon.

Date: September 13, 2010

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